IS 11331 (1985): Electrical Muscle and Nerve Stimulators for Therapeutic Purpose [MHD 19: Immuno-Biological Diagnostic Kits]

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Indian Standard

SPECIFICATION FOR ELECTRICAL MUSCLE AND NERVE STIMULATORS FOR THERAPEUTIC PURPOSE

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SPECIFICATION FOR ELECTRICAL MUSCLE AND NERVE STIMULATORS FOR THERAPEUTIC PURPOSE

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0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 11 June 1985, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 This standard specifies the requirements of therapeutic stimulators. The standard lays down the essential safety and performance requirements as well as methods of tests for therapeutic stimulators.

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1. SCOPE

1.1 This standard applies to electrical nerve or muscle stimulators for therapeutic use, intended for operation from a supply mains or from an internal electrical power source (batteries) which may or may not be rechargeable from a supply mains, or from combinations of such power sources.

2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions, in addition, to the definitions given in IS : 1885 (Part 43)-1977*, shall apply.

2.1 Applied Part — Electrodes and all parts permanently connected to them are regarded as the applied part of the equipment.

2.2 Diagnostic Stimulators — Electrical equipment with electrodes which are externally applied to a patient's skin (external electrodes) for the purpose of electrically stimulating either nerves or muscles, as appropriate by delivering electrical pulses to elicit responses (constant voltage types).

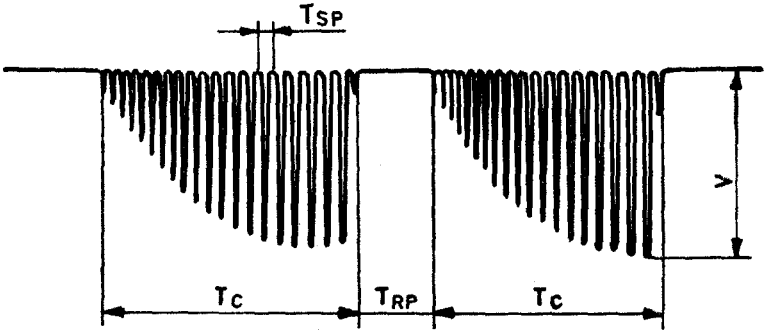
*Electrotechnical vocabulary: Part 43 Electrical equipment used in medical practice.

2.3 Therapeutic Stimulators — Electrical equipment with electrodes which are externally applied to a patient's skin (external electrodes) for the purpose of electrical stimulation by passing known pulse currents through the tissue (constant current types).

2.4 Galvanic Current — DC output of the stimulator with ripple content less than 0·01 percent peak to peak.

2.5 Interrupted Galvanic — Series of rectangular pulses which may be unmodulated output or non-ionising output.

2.6 Surged Faradism — A series of surge of pulses as shown in the Fig. 1.



T_c = time for contraction (stimulus),

T_{RP} = time of rest period (stimulus off),

T_{SP} = single pulse duration, and

V = maximum value of the pulse.

FIG. 1 WAVEFORM OF SURGED FARADISM

3. ENVIRONMENTAL CONDITIONS

3.1 Environmental Conditions — The provisions of IS : 8607 (Part 1)-1977* shall apply.

4. GENERAL AND SAFETY REQUIREMENTS

4.1 The relevant provision of all the parts of IS : 8607 shall apply. In addition the following additional precautions are to be taken.

4.2 Rectangular pulses are widely used in stimulators. They have the advantage that the waveform can readily be defined and measured. Many stimulators for clinical use may deliver up to 100 mA through intact skin. For this reason they are potentially lethal.

*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

4.2.1 Following precautions should be taken:

a) Labelling of the output controls and sockets to indicate the risk;

b) On-off warning lamp in mains operated apparatus;

c) Clear marking of the output control potentiometer so that the setting is obvious from a distance;

d) Maintenance of close spacing of the stimulating electrodes so that an excessive current flow will be localised. Similarly the patient ground electrode should be kept on the same limb as the stimulating electrodes; and

e) Untrained assistants should not use these instruments.

4.2.2 A stimulus output transformer which has been tested at 3 kv provides best protection against direct currents reaching the patient. The leads from the secondary winding to the output socket need to be routed at a distance from high voltage points.

4.2.3 A transformer cannot pass pulses with durations greater than a few milliseconds. With regard to stimulators, which produce pulses of longer duration a circuit designed to protect against the consequences of component failure is a contradiction in terms when physiological stimulating currents are themselves potentially lethal.

4.3 Circuit Diagrams — Circuit diagram and service manuals are essential for operation and maintenance.

5. GENERAL REQUIREMENTS FOR TESTS

5.1 The relevant provisions of IS : 8607 (Part 1)-1977* shall apply.

6. CLASSIFICATIONS

6.1 The relevant provisions of IS : 8607 (Part 1)-1977* shall apply.

7. MARKING, IDENTIFICATION AND INFORMATION

7.1 Marking on the Outside of the Equipment

7.1.1 The relevant provisions of IS : 8607 (Part 1)-1977* shall apply. In addition a label with the following inscription in *Red* shall be permanently affixed at a permanent place.

*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

CAUTION

'READ THE ACCOMPANYING DOCUMENTS/ INSTRUCTION BEFORE USE'

7.1.2 Equipment having an internal electrical power source or its separate battery charger shall be marked with a brief description of the procedure for the re-charging or replacement of the battery, full details shall be given in the instructions for use.

7.2 The following should be printed boldly in *Red* in the operating instruction:

'Electrical muscle stimulation should never be employed to the neglect of other methods, such as rest and proper splinting in early stages of nerve injury and muscle re-education and voluntary exercise in the stage of muscle and nerve re-generation. It should be considered at all times an adjunct and its administration should be entrusted only to technicians familiary with muscle physiology and pathology and fully instructed in proper technique. Improper application can bring about excessive stimulation of extremely weak muscles with set-back to recovery.'

NOTE — Cardiac fibrallation can be induced by alternating low frequency currents of low magnitudes. In electrical shock, cardiac fibrallation is regarded as the main cause of death. Patients with myocradial weakness seem especially sensitive to low frequency currents. Therefore, the invariable rule is never to apply low-frequency currents through the heart or with a technique that brings considerable current through the cardiac area.

7.3 Marking of Controls

7.3.1 In addition to the relevant provisions of **7.23** of IS:8607 (Part 1)-1977*, the requirements specified in **7.3.2** shall apply.

7.3.2 The control for selecting the output pulse shall be calibrated in terms of the amplitude of the pulse delivered to a resistive load of 500 ohms using a standard oscilloscope in the case of constant voltage stimulator. In the case of constant current stimulator, the output current shall be specified.

7.4 The equipment may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

7.5 Symbols

7.5.1 The provisions of IS : 8607 (Part 1)-1977* shall apply.

7.6 Identification of Supply Conductors

7.6.1 The provisions of **7.25** of IS : 8607 (Part 1)-1977* shall apply.

7.7 Indicator Light and Pulse Buttons

7.7.1 The provisions of **7.27** of IS : 8607 (Part 1)-1977* shall apply.

7.8 Accompanying Documents

7.8.1 The provisions of **7.28** of IS : 8607 (Part 1)-1977* shall apply in addition to those specified in **7.8.2** to **7.8.5.**

7.8.2 Full details of the wave forms of the delivered pulses when the stimulator is connected to a resistive load of 500 ohms, shall be given.

7.8.3 A description of the correct method of handling the electrodes in use shall be given.

7.8.4 For internally powered equipment, an advice on the periodic replacement of any primary or re-chargeable battery, and number of hours operation recommended must be spelt out. Additionally full details on the charging procedure of any re-chargeable battery shall be given.

7.8.5 A recommendation calling the user's attention to the need for periodic maintenance of the equipment, irrespective of usage, especially:

a) Cleaning of the electrodes and the insulating parts of the electrode handles,

b) Inspection of cables and electrode handles for possible insulation faults, and

c) Periodic functional checks.

8. POWER INPUT

8.1 The relevant provisions of IS : 8607 (Part 1)-1977* shall apply.

9. MECHANICAL SAFETY REQUIREMENT

9.1 The relevant provisions of IS : 8607 (Part 3)-1979† shall apply.

10. PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

10.1 The relevant provisions of IS : 8607 (Part 2)-1978‡ shall apply.

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*General and safety requirements for electrical equipment used in medical practice: Part 1 General.

†General and safety requirements for electrical equipment used in medical practice: Part 3 Protection against mechanical hazards.

‡General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against electric shock.

10.2 Leakage current flowing from each stimulating electrode separately to the body is dependent on the isolating transformer used in the instruments. The isolation resistance shall not be less than 10 MΩ.

10.2.1 Two paths exists for transmission of a fraction of the stimulating voltage to the recording electordes. They are (a) conductive transmission in the tissues. (Its contribution depends on the stimulating current, the location of the stimulating and recording electrodes and the part of the body under examination); and (b) ground currents (stimulus pulse generators require to be isolated from ground). The charging and discharging of the distributed capacitance between the isolation unit and ground causes currents to flow between subject and ground.

10.2.3 *Test* — The ground current can be measured with the stimulating, recording and ground electrodes properly positioned on the subject. A resistor (10-100 Ω) is interposed between the ground electrodes on the subject and the ground terminal. The voltage developed across this resistor during stimulation is measured with a differential amplifier. A reduction from 1 m A to 100/μ A or less can be obtained by using transformers with multiple screens.

10.3 Dielectric Strength and Insulation Resistance

10.3.1 The provisions of IS : 8607 (Part 2)-1978* shall apply.

11. PROTECTION AGAINST INFECTION

11.1 Electrodes and cables connected to them shall be cleaned, sterilised and disinfected in accordance with IS : 8607 (Part 6) - 1983†.

12. PROTECTION AGAINST INCORRECT OUTPUT

12.1 The stimulator shall be provided with an indication, preferably a current meter, to indicate the rms current used during stimulation (for constant current type). In case of constant voltage types, full stimulus output available across the electrode shall be specified for periodic cross checking.

12.2 Indication of Output

12.2.1 The indicated output and the measured output shall not deviate by more than ±5 percent.

Test: Measurement using measuring equipment providing an accuracy of better than 5 percent.

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*General and safety requirements for electrical equipment used in medical practice: Part 2 Protection against electric shock.

†General and safety requirements for electrical equipment used in medical practice: Part 6 Protection against excessive temperature air and other hazards.

12.3 Human Errors

12.3.1 Electrodes shall not be connected to the instrument when the energy storage device is being charged. Adequate care is taken in the design of the stimulator to ensure that no damage is caused even when the electrodes are shorted accidentaly while in use.

13. GENERAL AND CONSTRUCTIONAL REQUIREMENTS

13.1 The relevant provisions of IS : 8607 (Part 7)-1985* shall apply.

13.2 Arrangement of Function — Those controls and indicators required to bring the stimulator to operating condition shall be:

a) on/off switch (on/off indicator light must be provided),

b) stimulus select control, and

c) stimulus current indicator (meter).

13.3 Patient Electrodes — The electrode handle shall be constructed from an insulating material and the polarity of the stimulus shall be marked for convenience of the user. Ground electrode shall be made of brass, preferably nickle plated. Malleable lead can also be used for making the electrodes.

13.3.1 Cable shall be non-detachable with respect to the electrode handles. Anchorage shall be provided complying with the requirements for mains cords in IS : 8607 (Part 7)-1985*.

13.4 The mains supply cord shall be permanently attached to the stimulator via an appliance coupler complying with the requirement of the relevant Indian Standard.

13.5 The power input of mains powered equipment, averaged over any 2 seconds, shall be less than 50 W.

13.6 An output synchronising pulse shall be provided for the purposes of externally trigerring an electromyograph (*see* IS : 8885-1975†).

14. PERFORMANCE REQUIREMENTS

14.0 The stimulator shall have following performance requirements as given in **14.1**, **14.2** and **14.3**.

14.1 Galvanic Mode

Maximum output measured into 1 k Ω load = 60 mA

Output voltage = 60 V dc

Maximum ripple content = less than 0·01 percent peak to peak.

*General and safety requirements for electrical equipment used in medical practice: Part 7 Construction.

†Specification for electromyograph.

14.2 Interrupted Galvanic Mode

Pulse duration	0·01, 0·03, 0·1, 0·3, 1, 3, 10, 30, 100, 300 milliseconds
Pulse repetition rate	15, 30 per minute, 2, 3, 6, 12, 25, 50 per second
Output	0—150 V peak (continuously variable)

14.3 Surged Faradic Mode

Faradic pulse duration	1 millisecond
Faradic pulse repetition rate	40 to 50 per second
Contraction duration	2, 3, 4, 5 and 6 seconds in steps or continuously variable
Rest period	2, 3, 4, 5 and 6 seconds in steps or continuously variable
Max output measured into 1 k Ω load	Not less than 150 V peak

15. TEST FOR STIMULUS CURRENT

15.1 Testing Method — Between the stimulating elcctrode terminals, connect 1 k Ω resistor. One end of the resistor is grounded and the other end is connected to an oscilloscope, working in dc mode.

Monitor the waveform to check whether the stimulus strength or voltage is 60 volts (maximum), when maximum stimulus current becomes 60 mA.